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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
|-----------------|-------------|----------------------|---------------------|
|-----------------|-------------|----------------------|---------------------|

09/006,352 01/13/98 GENTZ

R PF454

022195
HUMAN GENOME SCIENCES, INC
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ROCKVILLE MD 20850

HM12/0828

EXAMINER

O HARA, E

ART UNIT

PAPER NUMBER

1646

17

DATE MAILED:

08/28/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

| | | | |
|------------------------------|-------------------------------|------------------------------|--|
| Office Action Summary | Application No. 09/006,352 | Applicant(s) GENTZ ET AL. | |
| | Examiner Eileen B. O'Hara | Art Unit 1646 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 June 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19-305 is/are pending in the application.
- 4a) Of the above claim(s) 19-23 and 160-284 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 19-305 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

1. Claims 19-305 are pending in the instant application.

Election/Restrictions

2. Applicant's election with traverse of Group I, claims 24-159 and 285-305, drawn to polynucleotides of TNFR-6alpha, in Paper No. 16 is acknowledged. Claims 19-23 and 160-284 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 16. Applicants' traversal of the restriction has been fully considered but has not been found persuasive in overcoming the restriction requirement. Applicants' argue that restriction remains improper unless it can be shown that the search and examination of the groups together would entail a "serious burden", that no such showing has been made, and that no arguments have been made explaining why it would impose an undue burden to examine the TNFR-6alpha and TNFR-6beta polypeptide claims together. Applicants assert that TNFR-6alpha and TNFR-6beta contain overlapping sequences and thus, the searches of these sequences would be overlapping. This is not found persuasive because although TNFR-6alpha and TNFR-6beta contain overlapping sequences, they still require non-overlapping, separate sequence searches, which would be burdensome. Therefore, restriction for examination purposes is proper and the restriction requirement is maintained.

Applicants claims are drawn to numerous patentably distinct nucleic acid sequences. Upon further consideration, further restriction *within* the formerly presented Invention I is required, as follows:

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The claims are drawn to numerous patentably distinct nucleic acids, each of which constitutes a patentably distinct product. Applicant is required to elect a single invention of a nucleic acid, selected from the group consisting of:(i.e. elect one from the following Markush group):a nucleic acid comprising a polynucleotide encoding a protein selected from the group consisting of the following regions of SEQ ID NO:2: Residues 1-300, 2-300, 31-300, 31-283, 49-300, 1-193, 31-46, 57-117, 132-175, 185-194, 205-217,239-264, 283-298, or a single ultimate species of a polynucleotide encoding a fragment of SEQ ID NO:2 wherein the fragment is at least ≥ 30 contiguous amino acids or ≥ 50 contiguous amino acids, or nucleotides 92-946 of SEQ ID NO: 1, or a nucleic acid molecule encoding one of the following amino acid sequences encoded by the cDNA contained in ATCC Deposit No. 97810, the full-length polypeptide, the full-length polypeptide excluding the amino-terminal methionine, the mature polypeptide, the soluble extracellular polypeptide, the complete amino acid sequence excluding up to 48 amino acids from the amino terminus, the complete amino acid sequence excluding up to 107 amino acids from the carboxy terminus, the complete amino acid sequence excluding up to 48 amino acids from the amino terminus and excluding up to 107 amino acids from the carboxy terminus. Applicants should note that in some cases multiple claims encompass one of the patentably distinct inventions set forth herein. It is presumed by the Examiner in setting forth this requirement that the nucleic acid of ATCC deposit 97810 is SEQ ID NO: 1.

To be fully responsive to this requirement, Applicants are **required** to point out which claims correspond to the elected invention.

Although the classifications for these various nucleic acids are overlapping, for instance 536/23.1, each represents a patentably distinct product with distinct physical and functional

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characteristics. Further, the search for more than one product would be burdensome, because most are claimed not by nucleic acid sequence, but by the sequence of the protein encoded thereby, and requires a search of the corresponding region of SEQ ID NO: 1 as well as a 'reverse translation' search of the corresponding region of SEQ ID NO: 2, such that each individual sequence requires two sequence searches which are not required for any of the other sequences, or alternatively by virtue of comprising only a small portion of a disclosed nucleic acid, which requires a separate "word search" of the nucleic acid databases. Due to the use of 'comprising' language, it cannot even be said that the search for nucleic acids encoding amino acids 1-300 of SEQ ID NO:2 would reveal art pertaining to, for instance a nucleic acid *comprising* a region encoding amino acids 185-194 of SEQ ID NO: 2, as the latter could be found embedded in a completely different protein. Accordingly, restriction is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eileen B. O'Hara, whose telephone number is (703) 308-3312. The examiner can normally be reached on Monday through Friday from 9:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached at (703) 308-6564.

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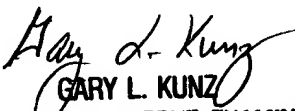
Official papers filed by fax should be directed to (703) 308-4242.

Informal papers filed by fax should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Eileen B. O'Hara, Ph.D.

Patent Examiner


GARY L. KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600